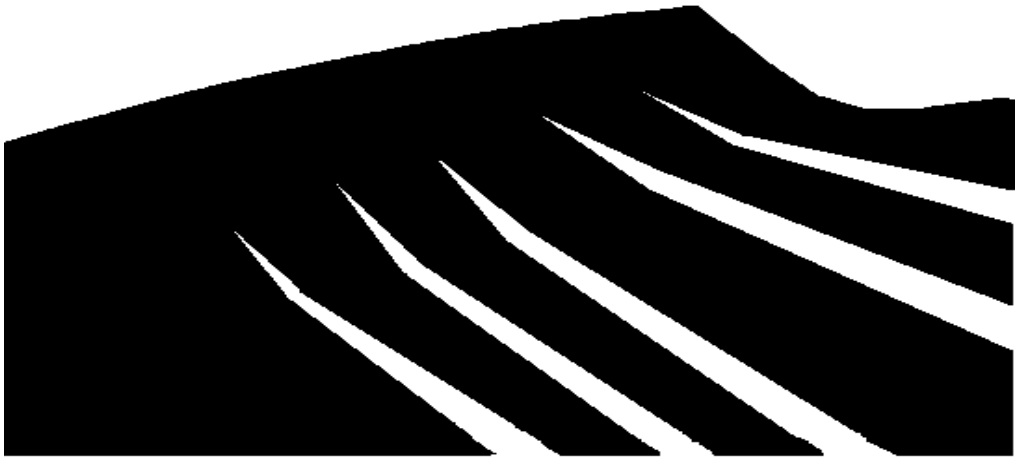
EFFECTIVE DATE	LANL-YMP-QP-06.2, R6
June 2, 1997	Page 1 of 8

PREPARATION, REVIEW AND APPROVAL OF QUALITY ADMINISTRATIVE PROCEDURES

LOS ALAMOS

QUALITY PROGRAM



APPROVAL FOR RELEASE	
M. J. CLEVENGER - PREPARER Signature on file	DATE Date on file
M. J. CLEVENGER - QUALITY ASSURANCE PROJECT LEADER Signature on file	DATE Date on file
G. Y. BUSSOD - LABORATORY LEAD Signature on file	DATE Date on file

Los Alamos
Yucca Mountain Site Characterization Project

HISTORY OF REVISIONS

REVISION NO.	EFFECTIVE DATE	PAGES REVISED	REASON FOR CHANGE
R0	10/10/90	All	Complete rewrite of QP-05.1
R1	09/30/91	All	Complete rewrite to address multiple QP Action Requests.
R2	01/31/94	All	Complete rewrite to streamline process, simplify forms, and to better define QARD requirements.
R3	06/15/94	All	Changed to address RTN Specialist review comments, and to better define QARD requirements.
R4	01/20/95	3, 5-8, & Att. 3	Review Criteria sheet no longer required as part of a record package (recommendation from DOE audit), and only TAPL review required for editorial changes.
R5	06/03/96	3, 4, 6, 7, 8, Atts. 2, 3, 4, 5, 6, 7	Changed to eliminate document control responsibilities in this procedure. Eliminated need to keep review comments.
R6	06/02/97	All	To address the new Technical Assurance and OQA staff responsibilities.

PREPARATION, REVIEW, AND APPROVAL OF QUALITY ADMINISTRATIVE PROCEDURES

1.0 PURPOSE

This procedure describes the process to prepare, review, approve, revise, or delete a quality administrative procedure (QP) for the Los Alamos National Laboratory (Los Alamos) Yucca Mountain Site Characterization Project (YMP or Project).

2.0 SCOPE

2.1 This procedure governs all Los Alamos YMP quality administrative procedures.

2.2 This procedure applies to all Los Alamos and Los Alamos-subcontractor YMP personnel (hereafter referred to as YMP personnel) who work under the Los Alamos YMP quality assurance program.

3.0 REFERENCES

LANL-YMP-QP-02.15, Requirements Traceability
LANL-YMP-QP-17.6, Records Management
DOE/RW-0333P, Office of Civilian Radioactive Waste Management Quality Assurance Requirements and Description (QARD)

4.0 DEFINITIONS

4.1 Quality Administrative Procedure (QP)

A QP is an implementing document that describes the process used to conduct Los Alamos YMP activities as required by the QARD. A revision is any change to the text or attachments of an existing QP that results in an increment of the revision number of the QP. Revisions follow the same review and approval process as a new QP. A QP is deleted by its cancellation and removal from the Los Alamos YMP document control system. Deleted procedures are not superseded.

5.0 RESPONSIBILITIES

The following personnel are responsible for activities identified in Section 6.0 of this procedure.

- Laboratory Lead (LL) and supervisors of affected organizations
- Technical Assurance Project Leader (TAPL)
- YMP personnel who initiate a QP Action Request
- QP preparer
- Office of Quality Assurance (OQA) representative
- Requirements Traceability (RT) Specialist

6.0 PROCEDURE

The use of this procedure must be controlled as follows:

- If this procedure cannot be implemented as written, YMP personnel should notify appropriate supervision. If it is determined that a portion of the work cannot be accomplished as described in this QP, or would result in an undesirable situation, that portion of the work will be stopped and not resumed until this procedure is modified or replaced by a new document that reflects the current work practice.

- Employees may use copies of this procedure printed from the controlled document electronic file; however, employees are responsible for assuring that the correct revision of this procedure is used.

- When this procedure becomes obsolete or superseded, it must be destroyed or marked "superseded" to ensure that this document is not used to perform work.

6.1 Request for a New QP, QP Revision, or QP Deletion.

6.1.1 **YMP personnel** request a new QP, revision to an existing QP, or deletion of an existing QP by completing Section I of a QP Action Request (Attachment 1). For a new QP, leave the QP identifier, current revision number, and title lines blank.

6.1.2 After receiving the QP Action Request, the **TAPL** ensures that the information in Section I is complete and correct, reviews document history and determines whether the proposed action is warranted.

6.1.3 If the action is warranted, the **TAPL** completes Section II of the QP Action Request, and:

6.1.3.1 For a new QP, enter in Section I the QP identifier (which is obtained from a Document Control representative), the revision level (which will be zero), and the QP title. For both a new QP or a QP revision proceed to subsection 6.2

6.1.3.2 For a QP deletion proceed to subsection 6.4.

NOTE: If appropriate, sends an information copy to the originator.

OR

6.1.4 If the action is not warranted, the **TAPL** does the following:

6.1.4.1 Check the "do not approve" box in Section II of the QP Action Request and enter the reason for disapproving.

6.1.4.2 Enter "N / A" for the assigned preparer, sign and date Section II of the form. Check "N / A" in Section III.

6.1.4.3 Send an information copy to the originator. No further action is required.

6.2 Preparation of a New QP or QP Revision

6.2.1 The **TAPL** ensures that QPs are prepared and maintained as required to implement quality program requirements. To initiate preparation of a new QP or revision of an existing QP, the TAPL forwards copies of the QP Action Request and other pertinent background information to the preparer.

6.2.2 For creation of a new QP, the **preparer** prepares a draft of the QP in accordance with Attachment 2 and ensures that "DRAFT" appears on the QP.

OR

6.2.3 For revision of an existing QP, the **preparer** revises the QP in accordance with Attachment 2 and indicates the changes in the procedure text by placing a vertical bar in the margin next to changes; if changes are typographical, or affect the majority of the text of the procedure, change bars are unnecessary. The preparer ensures that "DRAFT" appears on the QP.

NOTE: Changes to the procedure, in addition to those requested on the QP Action Request, may be made by the preparer when the draft is prepared. It is possible that changes approved by the TAPL on the QP Action Request may not be incorporated as a result of the QP review process.

6.3 Review and Approval of a New QP or QP Revision

6.3.1 To initiate a QP review, the **preparer** completes Section I of the QP Review Results (Attachment 3) and forwards a copy of it, a copy of the draft QP, a QP Review Sheet (Attachment 4) and the QP Review Criteria (Attachment 5), to the TAPL. Supplemental criteria may be added to the QP Review Criteria if appropriate.

6.3.2 The **TAPL** reviews the draft QP and may determine that the changes are not substantive and that they are editorial in nature (i.e., do not affect the general process). Examples of editorial corrections include grammar or spelling corrections, renumbering sections or attachments, changing the title or document number, or updating organizational changes. If so determined, the TAPL documents on a review sheet that the changes are not substantive and further review is not required. The TAPL returns the draft QP and review sheets to the preparer.

6.3.2.1 The **preparer** proceeds to subsection 6.3.5.3.

OR

6.3.3 The **TAPL** forwards copies of the QP Review Results, QP Review Sheet, the QP Review Criteria, the draft QP, and any pertinent background information to the supervisors of affected organizations and to an OQA representative.

6.3.4 The **affected organizations and** OQA **representative** conduct a review, and forward to the preparer, the completed QP Review Results, and when appropriate the QP Review. The review must be performed by individuals other than the originator

6.3.5 The **preparer** does the following:

6.3.5.1 Resolve review comments and document resolution of these comments on the review sheet. If the resolution of comments significantly change procedural implementation, repeat subsection 6.3 as appropriate. If the no comment box in Section II was selected, Section III is completed and reviewer line is filled in as "N/A."

6.3.5.2 Forward QP Review Results and QP Review Sheets to reviewers for completion of Section III of the QP Review Results as appropriate. Obtain from the reviewer, the completed QP Review Results, and if applicable, the completed QP Review Sheets.

6.3.5.3 Prepare a final version of the QP. Change bars are not required for the final version.

6.3.5.4 Sign and date the Title page (Attachment 6).

6.3.5.5 Forward a copy of the final QP to the TAPL.

6.3.6 The **TAPL** ensures Requirements Traceability Matrix input is prepared and reviewed for the new or revised QP in accordance with QP-02.15.

6.3.7 Once the QP meets applicable QARD requirements, the TAPL obtains the **OQA representative's** signature and date on the title page, obtains the Laboratory Lead's signature and date on the title page, and forwards a hard copy and an electronic copy of the approved QP to a document control representative.

6.3.8 The **preparer** prepares a record package consisting of the records listed in subsection 7.1 and submits it in accordance with QP-17.6.

NOTE: The QP Review Criteria does not become part of the record package unless supplemental review criteria are added.

6.4 Deletion of a QP

6.4.1 To delete a QP, the **TAPL** performs the following:

6.4.1.1 Check "N/A" in Section II of the QP Action Request.

6.4.1.2 Forwards a copy of the QP Action Request to the supervisors of affected organizations, to the RT Specialist, OQA representative, and to the Laboratory Lead for review.

6.4.1.3 The **supervisors, RT Specialist, OQA representative, and Laboratory Lead** review the proposed QP deletion, complete Section III of the QP Action Request, and return the form to the TAPL.

6.4.1.4 If the reviewers agree that the QP should be deleted, the **TAPL** forwards a copy of the QP Action Request to a document control representative and prepares and submits in accordance with QP-17.6, a record package consisting of the records listed in subsection 7.2.

OR

6.4.1.5 If a reviewer does not agree that the QP should be deleted, the QP remains active.

7.0 RECORDS

The following records generated from this procedure are submitted as a record package.

7.1 New or Revised QP

- Draft QP
- QP Review Results
- QP Review Criteria (only if supplemental review criteria are added)
- Final approved QP
- Pertinent correspondence related to these documents

7.2 Deleted QP

- QP Action Requests, signed by supervisors, QOA representative, RT Specialist and the Laboratory Lead, as appropriate.
- Pertinent correspondence related to these documents

8.0 TRAINING REQUIREMENTS

8.1 Prior to conducting work described in Section 6.0, the TAPL, QP preparer, OQA representative, and RT Specialist, require training to this procedure. Training to this procedure is accomplished by “read only.”

8.2 Since instructions are provided on the appropriate forms, the following personnel are not required to train to this procedure: employees (originator) who complete only Section I of a QP Action Request; QP reviewers (except for the OQA representative and RT Specialist); supervisors and the Laboratory Lead.

9.0 ATTACHMENTS

Attachment 1: QP Action Request (1 page)
Attachment 2: QP Organization (4 pages)
Attachment 3: QP Review Results (1 page)
Attachment 4: QP Review Sheet (1 page)
Attachment 5: QP Review Criteria (1 page)
Attachment 6: QP Title (1 page)
Attachment 7: History of Revisions (1 page)

QP ACTION REQUEST

SECTION I. ACTION REQUESTED (Originator completes as appropriate)

☐ NEW QP ☐ REVISE EXISTING QP ☐ DELETE EXISTING QP

DESCRIPTION OF, AND REASON FOR ACTION:

QP: _____ (Identifier) _____ (Rev.) _____ (Title)

ORIGINATOR: _____ (Print name) _____ (Signature) _____ (Date)

RETURN THIS FORM TO THE TECHNICAL ASSURANCE PROJECT LEADER, MS J521

SECTION II. (TAPL approval and assignment) ☐ NA

☐ APPROVE ☐ DO NOT APPROVE

REASON FOR DISAPPROVAL:

ASSIGNED PREPARER: _____ (Print name)

TAPL: _____ (Print name) _____ (Signature) _____ (Date)

SECTION III. (Deletion of QP) ☐ NA

AFFECTED ORGANIZATION

☐ SITE AND REGULATORY ☐ ADMINISTRATION ☐ TA ☐ TCO

☐ LL ☐ RT SPECIALIST ☐ OQA REPRESENTATIVE

☐ APPROVE DELETION ☐ DO NOT APPROVE DELETION

REASON FOR DISAPPROVAL:

NAME _____ (Print name) _____ (Signature) _____ (Date)

SEND THIS FORM TO THE TECHNICAL ASSURANCE PROJECT LEADER, MS J521

QP ORGANIZATION

A. Each QP must contain, at a minimum, the following components: Title page, History of Revisions page, and sections that address purpose, scope, references, definitions, responsibilities, procedure, records, training requirements, and attachments (if any). Follow the criteria in this attachment to prepare a draft and final QP.

B. TITLE PAGE

The QP title page (Attachment 6) provides a space for the effective date of the QP, and spaces for signatures of the preparer, OQA Representative and Laboratory Lead.

C. HISTORY OF REVISIONS

The "History of Revisions" page (Attachment 7) includes all the revision numbers (beginning with 0), effective dates, reason for change, and, if applicable, information regarding superseded procedures.

NOTE: The effective date on the Title page and the effective date on the History of Revisions page are entered by a document control representative.

D. HEADER BLOCK

Each page has a header block that contains the QP number, revision, and pagination (e.g., Page 1 of x, where x indicates a sequential page number).

E. QP TITLE

The title indicates the primary activities conducted through the QP.

F. QP NUMBER

The QP number is a unique alphanumeric identifier configured as follows:

LANL-YMP-QP-yy.zz, Rn, where

LANL-YMP indicates a Los Alamos YMP document (previous or subsequent changes to this identifier are not considered to refer to different QPs)
QP indicates a Quality Administrative Procedure
yy indicates the Los Alamos quality assurance program element that the QP addresses
.zz is a sequential number
R is an abbreviation for revision
n is the QP revision number (0 indicates the initial QP)

If the title of a procedure is changed, it is considered a new procedure and must receive a new number.

G. NOTES

Notes provide explanations or additional information and are entered into the text as follows:

NOTE: This is an example of how to insert a note into the text of a QP.

H. TEXT

The text of the QP follows a numerical, decimal, section-subsection format not to exceed three decimal points (e.g., 1.4.1.1). If an additional subsection is needed, it is prefixed with a lowercase alphabetical character (i.e., “a,” “b,” “c”). The following sections are required in all QPs.

1.0 PURPOSE

Describe the process that the QP addresses.

2.0 SCOPE

Define the limits of the QP's applications regarding affected activities and organizations (for clarity, specific exclusions may be stated). This section may also provide instructions for transition to the revised procedure.

3.0 REFERENCES

List, by document number and title, the references cited in Sections 4.0 through 9.0.

4.0 DEFINITIONS

Provide definitions for terms specific to the QP. Consider using QARD definitions and avoid redefining existing terms.

5.0 RESPONSIBILITIES

Identify, by YMP position title, (e.g., Technical Assurance Project Leader, Training Coordinator, etc.), the personnel responsible for implementing the activities described in Section 6.0, PROCEDURE, of the QP. If it is not practical to list specific YMP position titles, refer to individuals in general terms, (e.g., YMP personnel, technical assurance representative, etc.).

6.0 PROCEDURE

Provide clear, concise, step-by-step instructions for performing activities and the person responsible for performing each activity (identify the responsible person by generic title or YMP position title). The preparer is responsible for determining the appropriate level of detail. As appropriate, include controls for altering the sequence of activities.

In addition, the following information must be included at the beginning of Section 6.0:

The use of this procedure must be controlled as follows:

- If this procedure cannot be implemented as written, YMP personnel should notify appropriate supervision. If it is determined that a portion of the work cannot be accomplished as described in this QP, or would result in an undesirable situation, that portion of the work will be stopped and not resumed until this procedure is modified or replaced by a new document that reflects the current work practice.

- YMP personnel may use copies of this procedure printed from the controlled document electronic file; however, YMP personnel are responsible for assuring that the correct revision of this procedure is used.

- When this procedure becomes obsolete or superseded, it must be destroyed or marked "superseded" to ensure that this document is not used to perform work.

7.0 RECORDS

List the documents generated by the QP that are quality assurance records as defined in QP-17.6, and state whether the record is to be submitted to a Records Processing Center as a stand-alone record or as part of a record package.

8.0 TRAINING REQUIREMENTS

Specify the individuals listed in Section 5.0 who must be trained to the QP before performing the activities described in the QP. Identify the type of training required (e.g., read only or formal). If applicable, specify the individuals mentioned in the procedure who do not need to be trained to the QP and indicate why training is not required.

9.0 ATTACHMENTS

List each form or document identified in the QP as an "Attachment" using its attachment number, title, and number of pages as in the following example:

Attachment 1: Quality Assurance Review Checklist (1 page)

ATTACHMENTS

Forms, figures, examples, and supplementary documents to the QP are included as attachments. Attachments are titled with the same titles as those listed in Section 9.0 of the QP. Attachments are numbered sequentially (i.e., "Attachment 1," "Attachment 2") and are placed in sequential order after the last page of the QP. Each attachment has its own pagination that is not included with the pagination of the QP (e.g., the first page of a three-page attachment would be labeled "Page 1 of 3"). Each attachment has a header that contains the QP number and revision, attachment number, and pagination in the upper corner, as in the following example:

When a form is distributed as an attachment in an approved QP, the word “Example” will appear on the form. Attachments that provide information (e.g., this attachment) should not be marked with the word “Example.”

QP REVIEW RESULTS

SECTION I. (Preparer completes)

QP IDENTIFIER: _____ REVISION: _____ TITLE: _____

_____

PREPARER'S NAME: _____ PHONE: _____ MS: _____ DUE BY: _____
Print name

SEND THIS FORM TO THE TECHNICAL ASSURANCE PROJECT LEADER, MS J521

SECTION II. (Reviewer completes)

REVIEWER INSTRUCTIONS:

1. Review the QP against the attached Review Criteria.
2. For comments, enter the location of the section in question and the proposed actions on the attached review sheet. If no comments, check the "No Comments" box, and check the N/A box in Section III.
3. Any changes to original entries must be initialed and dated.
4. Complete Section II, return the review sheets to the preparer identified in Section I.
5. After the procedure is modified, the reviewer completes Section III, as appropriate.

I HAVE FOLLOWED THE INSTRUCTIONS FOR REVIEWING THIS DOCUMENT. ☐ Comments Attached ☐ No Comments

REVIEWER: _____ _____ _____ _____
Print name Signature Phone Date

SECTION III. Signatures below indicate that all comments have been satisfactorily resolved.

REVIEWING ORGANIZATION: (Check One)

☐ SITE & REGULATORY ☐ ADMINISTRATION ☐ OQA ☐ TCO ☐ LL ☐ RT SPECIALIST

REVIEWER: _____ _____ ☐ N/A
Signature Date

AFTER COMPLETING SECTION III, RETURN REVIEW SHEETS TO THE PREPARER IDENTIFIED IN SECTION I.

QP REVIEW SHEET

IDENTIFIER: _____ REVISION: _____ REVIEWER: _____

LOCATION	PROPOSED ACTION	RESOLUTION

QP REVIEW CRITERIA

CONSIDER THE CRITERIA BELOW, AS APPROPRIATE, AND DOCUMENT YOUR COMMENTS ON THE REVIEW SHEET.

SECTION I. GENERAL REVIEW CRITERIA

1. Is the QP applicable for the process it addresses?
2. Are the steps and instructions adequate, correct, complete, accurate and understandable?
3. Does each step clearly indicate who (by position title or generic title) is to perform the step?
4. Are all the required documents resulting from the procedure listed?

SECTION II. TECHNICAL ASSURANCE REVIEW CRITERIA

1. Does the QP conform to QP-06.2 requirements?
2. Are the QP references/definitions cited correctly?
3. Does the QP affect other QPs?

SECTION III. OQA REVIEW CRITERIA

1. Is the QP sufficiently detailed to be implemented?
2. Does the QP adequately address applicable QARD requirements?

EFFECTIVE DATE	LANL-YMP-QP-yy.zz, Rn Page 1 of x

QP TITLE

LOS ALAMOS
QUALITY PROGRAM

CONCURRENCE FOR RELEASE	
NAME - PREPARER	DATE
NAME - OQA REPRESENTATIVE	DATE
NAME - LABORATORY LEAD	DATE

Los Alamos
Yucca Mountain Site
Characterization Project

HISTORY OF REVISIONS

REVISION NO.	EFFECTIVE DATE	PAGES REVISED	REASON FOR CHANGE
R0		N/A	Initial procedure.